UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN FRANCISCO DIVISION)

IN RE: VIAGRA (SILDENAFIL CITRATE) AND CIALIS (TADALAFIL) PRODUCTS LIABILITY LITIGATION	Case No. 16-md-02691-RS MDL No. 2691
This Document Relates to: ALL ACTIONS	**PRETRIAL ORDER NO. 17: DEFENDANT FACT SHEETS**

IT IS HEREBY ORDERED that:

1. **Scope of Order.** This Order governs the completion and execution of Defendant Fact Sheets ("DFS") and the production of related documents by Defendants. This Order shall govern the cases: (1) transferred to this Court by the Judicial Panel on Multidistrict Litigation ("JPML"), pursuant to its Order(s) of April 7, 2016 and December 7, 2016; (2) transferred to this Court by the JPML pursuant to Rule 7.4 of the Rules of Procedure of that Panel; or (3) directly filed in this Court, transferred, or properly removed to this Court. This Order is binding on all parties and their counsel in all cases currently pending or subsequently made a part of these MDL Proceedings and shall govern each case in the proceedings.

Nothing in the DFS shall be deemed to limit the scope of inquiry at depositions or the admissibility of evidence at trial. The scope of inquiry at depositions shall remain governed by

the Federal Rules of Civil Procedure. The admissibility of information provided in responding to the DFS shall be governed by the Federal Rules and no objections are waived by virtue of any DFS response.

2. **Service of DFSs and Responsive Documents.** With respect to each Plaintiff in each case in which Pfizer Inc and/or Eli Lilly and Company have been named as a Defendant and served with the operative complaint, each such defendant named and served shall complete and serve upon Plaintiff a DFS, in the form attached as Exhibit 1 with Responsive Documents through MDL Centrality and in accordance with Pretrial Order No. 16 (Document 820 filed on December 12, 2018).

SO ORDERED.

Dated: 8/12/19

THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MDL No. 2691
In Re: Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation

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Defendant Fact Sheet

For each filed case in which the specific Defendant(s), Pfizer Inc and/or Eli Lilly Company, is named, the Defendant(s) must complete this Defendant Fact Sheet ("DFS") and identify (by document number) or provide documents and/or data responsive to the questions set forth below to the best of their knowledge and in good faith. Please identify any documents that you are producing as responsive to a question or request by document number. Within 120 days of the latest of (1) entry of this order, (2) receiving a Verified Plaintiff Fact Sheet ("PFS"); or (3) the deadline set forth in Amended Pretrial Order 15 (Document 918 filed on April 9, 2019), Defendants must complete and serve this DFS as set forth within this Pretrial Order and in Pretrial Order No. 16 (Document 820 filed on December 12, 2018). Any Defendant may request one extension of thirty (30) days to serve a completed DFS, which the Plaintiff(s) shall not unreasonably withhold. Such requests must be made in writing via email to Plaintiff's counsel with a simultaneous copy to Plaintiff's Fact Sheet designated Counsel before the expiration of the deadline. In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary.

Each Defendant's DFS responses are made subject to the Protective Order entered in this litigation. Unless otherwise marked as Highly Confidential, all information disclosed in a DFS, the DFS itself, and all related documents or information produced pursuant to the DFS shall be deemed confidential and treated as "Confidential Information" as defined in the Protective Order. Additionally, some of the information produced may be redacted to protect the privacy rights of third parties.

Definitions

YOU, YOUR or YOURS: As used herein, these terms mean the responding Defendant(s).

DEFENDANT(S): As used herein, this term means Pfizer Inc and/or Eli Lilly and Company.

VIAGRA®/REVATIO®: The two drugs are part of a class of drugs known as PDE5 inhibitors. The active ingredient in both is sildenafil and the manufacturer is Pfizer Inc

CIALIS®/ADCIRCA®: These two drugs are part of a class of drugs known as PDE5 inhibitors. The active ingredient in both is tadalafil and the manufacturer is Eli Lilly and Company.

CALL NOTES: Entries in Defendant's call notes database(s) reflecting contacts with Prescribing Healthcare Providers related to Viagra®/Revatio® (as to Pfizer Inc's DFS response) or Cialis®/Adcirca® (as to Eli Lilly and Company's DFS response).

KEY OPINION LEADER or **THOUGHT LEADER**: Physicians, often academic researchers, who are believed by Defendant(s) to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by Defendant(s) to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, author or contribute to articles or abstracts, sit on advisory boards and make presentations on their behalf at regulatory meetings or hearings.

RELEVANT TIME PERIOD: From five (5) years prior to the date on which Plaintiff was first prescribed Viagra®/Revatio® (as to Pfizer Inc's DFS response) or Cialis®/Adcirca® (as to Eli Lilly and Company's DFS response) as set forth in PFS Section III.A.7 through the later of (1) date of the last prescription of Viagra®/Revatio® (as to Pfizer Inc's DFS response) or Cialis®/Adcirca® (as to Eli Lilly and Company's DFS response) to Plaintiff, as set forth in PFS Section III.A.7, or (2) the date of Plaintiff's Alleged Injury as set forth in PFS Section IV.A.

REMUNERATION: Anything of monetary value greater than $50 in cash or in kind, but specifically excludes samples, discounts and rebates, in-kind items for charity care, educational materials intended for patients, medical devices loaned for clinical trials, and warranty services.

SALES REPRESENTATIVE: Any person presently or formerly engaged or employed by Defendant(s) whose job duties include calling on physicians or other healthcare professionals, healthcare facilities, hospitals, and/or physician practice groups for the purpose of promoting Viagra®/Revatio® (as to Pfizer Inc's DFS response) or Cialis®/Adcirca® (as to Eli Lilly and Company's DFS response) to physicians or other healthcare providers.

PRESCRIBING HEALTHCARE PROVIDER: Any provider of healthcare, including but not necessarily limited to physicians, general practitioners, medical specialists, medical doctors, surgeons, plastic surgeons, nurses, nurse practitioners, physician assistants, rehabilitation specialists, physical therapists, occupational therapists, counselors and pharmacists, identified in the PFS Section III.A.7 as a Prescribing Healthcare Provider who prescribed Viagra®/Revatio® and/or Cialis®/Adcirca® to the Plaintiff.

TREATING HEALTHCARE PROVIDER: Any provider of healthcare, including but not necessarily limited to physicians, general practitioners, medical specialists, medical doctors, surgeons, plastic surgeons, nurses, nurse practitioners, physician assistants, rehabilitation specialists, physical therapists, occupational therapists, counselors and pharmacists, identified in the PFS Section IV and/or PFS Section V.A.

VERIFIED PLAINTIFF FACT SHEET: A Plaintiff Fact Sheet is deemed verified if it (1) is served in the manner set forth by Pretrial Orders 15 (Document 804 filed on November 30, 2018 as amended by Document 918 filed on April 9, 2019) and 16 (Document 820 filed on December 12, 2018); (2) is substantially complete, (that is, a reasonable effort has been made to answer each question in good faith, even if Plaintiff can only answer the question with responses such as "cannot recall," "not applicable," "I don't know," or "unknown"); and (3) includes the required completed verification, authorizations, and documents identified in Section VIII of the Plaintiff Fact Sheet.

I. CASE INFORMATION

This DFS pertains to the following case:

Case Caption: _____

MDL Case Number: _____

DFS Completion Date: _____

DFS Supplement Date: _____

II. CONTACTS WITH HEALTHCARE PROVIDERS

A. Healthcare Provider Information Request Letters. For each Prescribing Healthcare Provider and Treating Healthcare Provider identified in the PFS, please provide the following information.

If any of Plaintiff's Prescribing Healthcare Provider(s) and/or Treating Healthcare Provider(s) has (have) initiated a request for information regarding Viagra®/Revatio® and/or Cialis®/Adcirca® that is captured in a database, please identify or provide as an attachment to this DFS the (a) name and address of the requestor (i.e., the physician who contacted Defendant(s)); (b) the date of the inquiry, (c) the format of the inquiry, if available (d) the date of the response, if any, the person who responded including their title and department, if available in the relevant database(s), and (e) the address to which the response was sent (i.e., fax number, mailing address); and produce the document(s) reflecting that written inquiry and any document sent in response, if available:

Original PIR or Request Document Date	Date Response Sent	Identity of Individual who Made Request/ Response Recipient (Name & Address)	Identity of Sender (Name & Address, Title and Department, if available)	Bates Number of Supporting Documentation

B. Other Contacts.

1. **Call Notes.**

(a) Identify by name any of the Defendants' Sales Representatives who called on the Prescribing Healthcare Provider(s) in any way related to Viagra®/Revatio® and/or Cialis®/Adcirca® during the Relevant Time Period and please provide dates of each contact (or produce report listing the same).

To the extent that the Relevant Time Period includes dates prior to January 1, 2005: (1) If Plaintiff's claims are covered by Sections A and B of Amended Pretrial Order 15 (Document 918), Defendant Lilly shall respond in supplement to this query with respect to those dates on or before December 28, 2019. (2) If Plaintiff's claims are covered by Section C of Amended Pretrial Order 15 (Document 918), Defendant Lilly shall respond in supplement to this query as follows:

- Verified Plaintiff Fact Sheets received between January 1 through April 30 of each calendar year shall be responded to by Defendant Lilly by the last day of August of that calendar year.

- Verified Plaintiff Fact Sheets received between May 1 through August 31 of each calendar year shall be responded to by Defendant Lilly by the last day of December of that calendar year.

- Verified Plaintiff Fact Sheets received between August 1 through December 31 of each calendar year shall be responded to by Defendant Lilly by the last day of April of that calendar year.

Name of Prescribing Healthcare Provider Contacted	Name of Sales Representative	Date(s) of each Contact with Prescribing Healthcare Provider

(b) For each Sales Representative identified in this DFS, please produce for the Relevant Time Period Call Notes, if any, for each contact between the Prescribing Healthcare Provider and the Sales Representative related to and/or regarding Viagra®/Revatio® and/or Cialis®/Adcirca® in a format that Plaintiffs' Counsel can search and review electronically.

To the extent that the Relevant Time Period includes dates prior to January 1, 2005: (1) If Plaintiff's claims are covered by Sections A and B of Amended Pretrial Order 15 (Document 918), Defendant Lilly shall respond in supplement to this query with respect to those dates on or before December 28, 2019. (2) If Plaintiff's claims are covered by Section C of Amended Pretrial Order 15, Defendant Lilly shall respond in supplement to this query as follows:

- Verified Plaintiff Fact Sheets received between January 1 through April 30 of each calendar year shall be responded to by Defendant Lilly by the last day of August of that calendar year.

- Verified Plaintiff Fact Sheets received between May 1 through August 31 of each calendar year shall be responded to by Defendant Lilly by the last day of December of that calendar year.

- Verified Plaintiff Fact Sheets received between August 1 through December 31 of each calendar year shall be responded to by Defendant Lilly by the last day of April of that calendar year.

2. **Dear Healthcare Provider Letters**. Please produce through MDL Centrality any Dear Doctor, Dear Healthcare Provider, Dear Colleague or similar type of letter or document sent by Defendants regarding Viagra®/Revatio® and/or Cialis®/Adcirca®.

3. **Samples.** If Plaintiff indicated in the PFS receipt of samples of Viagra®/Revatio® and/or Cialis®/Adcirca®, have Defendants or their Sales Representatives provided any Viagra®/Revatio® (if receipt of Viagra®/Revatio® samples was indicated in the PFS) and/or Cialis®/Adcirca® samples (if receipt of Cialis®/Adcirca® samples was indicated in the PFS) to Plaintiff's Prescribing Healthcare Provider(s) identified in the PFS during the Relevant Time Period?

   Yes ☐ No ☐ Not Applicable ☐

   If the above answer is "Yes," please identify below or produce as an attachment a report containing, for the Relevant Time Period:

   a. The Prescribing Healthcare Provider(s) identified in the PFS that received the samples.
   b. The date(s) on which such samples were provided.
   c. The product name, amount and dosage of each sample.
   d. The name of the Sales Representative(s) or Department who provided the samples.

To the extent that the Relevant Time Period includes dates prior to January 1, 2005: (1) If Plaintiff's claims are covered by Sections A and B of Amended Pretrial Order 15 (Document 918), Defendant Lilly shall respond in supplement to this query with respect to those dates on or before December 28, 2019. (2) If Plaintiff's claims are covered by Section C of Amended Pretrial Order 15 (Document 918), Defendant Lilly shall respond in supplement to this query as follows:

- Verified Plaintiff Fact Sheets received between January 1 through April 30 of each calendar year shall be responded to by Defendant Lilly by the last day of August of that calendar year.

- Verified Plaintiff Fact Sheets received between May 1 through August 31 of each calendar year shall be responded to by Defendant Lilly by the last day of December of that calendar year.

- Verified Plaintiff Fact Sheets received between August 1 through December 31 of each calendar year shall be responded to by Defendant Lilly by the last day of April of that calendar year.

Prescribing Healthcare Provider	Name of Sales Representative or Department	Date Shipped and/or Provided	Product Name, Amount and Dosage

III. OTHER CONTACT AND CONSULTING WITH PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDER(S)

Consulting and Professional Relationships: If any of Plaintiff's Prescribing Healthcare Providers identified in the PFS have been provided with Remuneration by Defendant(s) as a Key Opinion Leader, Thought Leader, member of a speaker's bureau, clinical investigator or consultant, or speaker at a conference or Continuing Medical Education event, please identify, for the Relevant Time Period, the date(s) that each Prescribing Healthcare Provider was retained and/or remunerated; the nature of the affiliation; and the amount of any Remuneration and/or reimbursement for expenses.

Prescribing Health Care Provider	Date(s) Retained and/or Remunerated	Nature of Affiliation	Amount of Remuneration and/or Reimbursement	Reason for Remuneration

IV. PLAINTIFF'S PRESCRIBING HEALTHCARE PROVIDERS

For each Prescribing Healthcare Provider identified in the PFS, please state and produce the following:

A. Do you have documents or other information reflecting prescriber-level data (e.g. IMS data) in a database searchable by prescriber name that tracks or purports to track the prescribing practices of Plaintiff's Prescribing Healthcare Provider(s) identified in the PFS with respect to Viagra®/Revatio® and/or Cialis®/Adcirca®?

Yes ☐ **No** ☐

B. If the answer is "Yes," please provide a report containing, or identify below and produce, all such data for each of Plaintiff's Prescribing Healthcare Provider(s) identified in the PFS regarding Viagra®/Revatio® or Cialis®/Adcirca® for the Relevant Time Period, subject to the agreement with the data vendor to release the data, which approval and/or agreement Defendants will request, and subject to the execution of IQVIA's (or applicable vendor's) consent approval letter by Pfizer Inc and Lilly.

Prescribing Healthcare Provider	Tracking Information - Database, Document or Information Description	If Database Utilized, please identify name of tracking database	Document Number(s)

V. PLAINTIFF'S MEDICAL CONDITION

A. Is there a record or records in Defendants' Medical Information (as to Pfizer Inc) or The Lilly Answer Center (as to Lilly) databases documenting contact between Defendant and Plaintiff or anyone acting on Plaintiff's behalf (other than Plaintiff's counsel) concerning Plaintiff and Viagra®/Revatio® or Cialis®/Adcirca, prior to the date Plaintiff filed his or her lawsuit?

Yes ☐ No ☐

If the answer is "Yes," please identify below, or attach a report containing, the person(s) or entity who contacted Defendant, the person who communicated a response, if any, and the dates of the contact(s) and response(s), and identify and produce all documents from such databases created before the filing of this lawsuit which reflect such communications between any person and Defendant concerning Plaintiff.

Name and Address of Person Who Initiated Contact	Date of Contact	Name and Address of Person Communicating Response	Date of Response	Document Numbers of Supporting Documentation Related to Communications

B. Is there a record or records in Defendant's adverse event database, dated prior to the filing of this lawsuit, regarding an adverse event report pertaining to Plaintiff and the use of Viagra®/Revatio® and/or Cialis®/Adcirca®?

Yes ☐ No ☐

If the answer is "Yes," please produce a copy of such MedWatch form. MedWatch forms shall be redacted as necessary per federal law.

VI. FUTURE DOCUMENT PRODUCTION

To the extent that Plaintiff's case is selected for case-specific discovery involving additional, case-specific document production by Defendant, Defendant will produce without further need for document request by Plaintiff:

i. Any non-privileged documents that (1) are in collected case-specific custodial material, that is, they are in the custody of an agreed-upon case-specific document custodian and contain search terms to be agreed upon; (2) were created prior to the filing of Plaintiff's lawsuit; and (3) relate to or refer to Plaintiff; and

ii. Any non-privileged documents that (1) are in collected case-specific custodial material, that is, they are in the custody of an agreed-upon case-specific document custodian and contain search terms to be agreed upon; (2) were created prior to the filing of Plaintiff's lawsuit; and (3) track or purport to track the prescribing practices of Plaintiff's Prescribing Healthcare Provider(s) identified in the PFS with respect to Viagra®/Revatio® and/or Cialis®/Adcirca®.

CERTIFICATION

I, _____, am authorized to provide verification of discovery responses on behalf of Defendant _____. Some of the information and facts within this Defendant Fact Sheet is not within my personal knowledge. Such information has been assembled by authorized employees and/or counsel of _____, upon whose advice and information I relied and who have informed me that the information and facts are true and accurate. Therefore, I declare under penalty of perjury that the information as to the foregoing Defendant provided in this Defendant Fact Sheet is true and correct to the best of my knowledge upon information and belief.

Further, I acknowledge that I have an obligation to supplement the above responses, in accordance with the Federal Rules of Civil Procedure, if I learn that they are in some respect incomplete or incorrect.

_____ _____

Signature Date

_____

Print Name

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was electronically filed through the Court's CM/ECF system on June 24, 2019, which shall send notification of such filing to all CM/ECF participants.

/s/Rachel Abrams
Rachel Abrams